

-101-

We Claim:

1. A method of detecting the presence of a target CS141 polynucleotide in a test sample, comprising:

- 5 (a) contacting said test sample with at least one CS141-specific polynucleotide or complement thereof; and
(b) detecting the presence of said target CS141 polynucleotide in the test sample, wherein said CS141-specific polynucleotide has at least 50% identity with a polynucleotide selected from the group consisting of SEQUENCE ID NOS 1-13,
10 and fragments or complements thereof.

2. The method of claim 1, wherein said target CS141 polynucleotide is attached to a solid phase prior to performing step (a).

15 3. A method for detecting mRNA of CS141 in a test sample, comprising:

- (a) performing reverse transcription with at least one primer in order to produce cDNA;
(b) amplifying the cDNA obtained from step (a) using CS141
20 oligonucleotides as sense and antisense primers to obtain CS141 amplicon; and
(c) detecting the presence of said CS141 amplicon in the test sample, wherein the CS141 oligonucleotides utilized in steps (a) and (b) have at least 50% identity with a polynucleotide selected from the group consisting of SEQUENCE ID NOS 1-13, and fragments or complements thereof.

25 4. The method of claim 3, wherein said test sample is reacted with a solid phase prior to performing one of steps (a), (b), or (c).

5. The method of claim 3, wherein said detection step comprises
30 utilizing a detectable label capable of generating a measurable signal.

6. A method of detecting a target CS141 polynucleotide in a test sample suspected of containing said target, comprising:

(b) contacting said first stage reaction product with at least one other
5 CS141 oligonucleotide to obtain a second stage reaction product, with the proviso
that the other CS141 oligonucleotide is located 3' to the CS141 oligonucleotides
utilized in step (a) and is complementary to said first stage reaction product; and

7. The method of claim 6, wherein said test sample is reacted with a
15 solid phase prior to performing one of steps (a), (b), or (c).

20 9. The method of claim 8, wherein said detectable label is reacted to a solid phase.

11. A purified polynucleotide or fragment thereof derived from a CS141 gene, wherein said polynucleotide is capable of selectively hybridizing to the nucleic acid of said CS141 gene and has at least 50% identity with a sequence selected from the group consisting of (a) SEQUENCE ID NOS 1-9, SEQUENCE ID NO 12, SEQUENCE ID NO 13, and complements thereof, and (b) fragments of SEQUENCE ID NOS 1-9.

-103-

12. The purified polynucleotide of claim 11, wherein said polynucleotide is produced by recombinant techniques.

13. The purified polynucleotide of claim 11, wherein said polynucleotide is produced by synthetic techniques.

~~14. The purified polynucleotide of claim 11, wherein said polynucleotide comprises a sequence encoding at least one CS141 epitope.~~

*sub
AO*
15. A recombinant expression system comprising a nucleic acid sequence that includes an open reading frame derived from CS141 operably linked to a control sequence compatible with a desired host, wherein said nucleic acid sequence has at least 50% identity with a polynucleotide selected from the group consisting of ~~SEQUENCE ID NOS 1-13, and fragments or complements thereof.~~

16. A cell transfected with the recombinant expression system of claim 15.

17. A CS141 polypeptide having at least 60% identity with an amino acid sequence selected from the group consisting of SEQUENCE ID NO 24, SEQUENCE ID NO 25, SEQUENCE ID NO 26, SEQUENCE ID NO 27, SEQUENCE ID NO 28, and fragments thereof.

18. The polypeptide of claim 17, wherein said polypeptide is produced by recombinant techniques.

19. The polypeptide of claim 17, wherein said polypeptide is produced by synthetic techniques.

20. An antibody which specifically binds to at least one CS141 epitope, wherein said CS141 epitope is derived from an amino acid sequence having at least 50% identity with an amino acid sequence selected from the group consisting of SEQUENCE ID NO 24, SEQUENCE ID NO 25, SEQUENCE ID NO 26, SEQUENCE ID NO 27, SEQUENCE ID NO 28, and fragments thereof.

-104-

21. An assay kit for determining the presence of CS141 antigen or anti-CS141 antibody in a test sample, comprising a container containing a CS141 polypeptide having at least 50% identity with an amino acid sequence selected from the group consisting of SEQUENCE ID NO 24, SEQUENCE ID NO 25,
5 SEQUENCE ID NO 26, SEQUENCE ID NO 27, SEQUENCE ID NO 28, and fragments thereof.

22. The assay kit of claim 21, wherein said polypeptide is attached to a solid phase.
10

23. An assay kit for determining the presence of CS141 antigen in a test sample, comprising a container containing an antibody which specifically binds to a CS141 antigen which comprises at least one CS141 epitope.

24. The kit of claim 23, wherein said antibody is attached to a solid phase.
15

~~25. A method for producing a polypeptide comprising at least one CS141 epitope, said method comprising incubating host cells that have been transfected with an expression vector containing a polynucleotide sequence encoding a polypeptide, wherein said polypeptide comprises an amino acid sequence having at least 50% identity with an amino acid sequence selected from the group consisting of SEQUENCE ID NO 24, SEQUENCE ID NO 25, SEQUENCE ID NO 26, SEQUENCE ID NO 27, SEQUENCE ID NO 28, and fragments thereof.~~
20
25

26. A method for detecting CS141 antigen in a test sample suspected of containing said CS141 antigen, comprising:

(a) contacting the test sample with an antibody or fragment thereof which specifically binds to at least one epitope of a CS141 antigen selected from the group consisting of SEQUENCE ID NO 24, SEQUENCE ID NO 25, SEQUENCE ID NO 26, SEQUENCE ID NO 27, SEQUENCE ID NO 28, and fragments thereof, wherein said contacting is carried out for a time and under conditions sufficient for the formation of antibody/antigen complexes; and
30

(b) detecting said complexes.
35

SEQUENCE ID NO 24

sub
A3

-105-

27. The method of claim 26, wherein said antibody is attached to a solid phase.

28. A method for detecting the presence of antibodies specific for a
5 CS141 antigen in a test sample suspected of containing such antibodies, said method comprising:

(a) contacting the test sample with a CS141 polypeptide, wherein said CS141 polypeptide contains at least one CS141 epitope derived from an amino acid sequence or fragment thereof having at least 50% identity with an amino acid
10 sequence selected from the group consisting of SEQUENCE ID NO 24, SEQUENCE ID NO 25, SEQUENCE ID NO 26, SEQUENCE ID NO 27, SEQUENCE ID NO 28, and fragments thereof, and further wherein said contacting is carried out for a time and under conditions sufficient to allow antigen/antibody complexes to form; and

15 (b) detecting said complexes.

29. The method of claim 28, wherein said CS141 polypeptide is attached to a solid phase.

sub A4
20 ~~30. A cell transfected with a nucleic acid sequence encoding at least one CS141 epitope, wherein said nucleic acid sequence is selected from the group consisting of SEQUENCE ID NOS 1-13, and fragments or complements thereof.~~

25 31. A method for producing antibodies which specifically bind to CS141 antigen, comprising administering to an individual an isolated immunogenic polypeptide or fragment thereof in an amount sufficient to elicit an immune response, wherein said immunogenic polypeptide comprises at least one CS141 epitope and has at least 50% identity to a sequence selected from the group consisting of SEQUENCE ID NO 24, SEQUENCE ID NO 25, SEQUENCE ID NO
30 26, SEQUENCE ID NO 27, SEQUENCE ID NO 28, and fragments thereof.

32. A method for producing antibodies which specifically bind to CS141 antigen, comprising administering to an individual a plasmid comprising a sequence which encodes at least one CS141 epitope derived from a polypeptide having an
35 amino acid sequence selected from the group consisting of SEQUENCE ID NO 24,

-106-

SEQUENCE ID NO 25, SEQUENCE ID NO 26, SEQUENCE ID NO 27,
SEQUENCE ID NO 28, and fragments thereof.

33. A composition of matter comprising a CS141 polynucleotide or
5 fragment thereof, wherein said polynucleotide has at least 50% identity with a
sequence selected from the group consisting of (a) SEQUENCE ID NOS 1-9,
SEQUENCE ID NO 12, SEQUENCE ID NO 13, and complements thereof, and (b)
fragments of SEQUENCE ID NOS 1-9.

34. A composition of matter comprising a polypeptide containing at least
10 one CS141 epitope, wherein said polypeptide has at least 60% identity with a
sequence selected from the group consisting of SEQUENCE ID NO 24,
SEQUENCE ID NO 25, SEQUENCE ID NO 26, SEQUENCE ID NO 27,
SEQUENCE ID NO 28, and fragments thereof.

35. The test kit of claim 10 further comprising a container with tools
15 useful for collection of said sample, wherein the tools are selected from the group
consisting of lancets, absorbent paper, cloth, swabs and cups.

36. The assay kit of claim 21 further comprising a container with tools
20 useful for collection of said sample, wherein the tools are selected from the group
consisting of lancets, absorbent paper, cloth, swabs and cups.

37. The test kit of claim 23 further comprising a container with tools
25 useful for collection of said sample, wherein the tools are selected from the group
consisting of lancets, absorbent paper, cloth, swabs and cups.

38. A gene, or a fragment thereof, which codes for a CS141 protein
which comprises an amino acid sequence having at least 60% identity with
30 SEQUENCE ID NO 24.

39. A gene, or a fragment thereof, comprising DNA having at least 50%
identity with SEQUENCE ID NO 12 or SEQUENCE ID NO 13.

Handwritten signature: *Handwritten signature*

Handwritten signature: *Handwritten signature*